American College of Surgeons

Washington Office: 1640 Wisconsin Avenue, NW • Washington, DC 20007 • 202/337-2701 • FAX 202/337-4271
e-mail: postmaster@facs.org ACS Web site: http://www.facs.org

99D-2335

October 26, 1999

Jane Henney, MD
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Surgeon's Patient Examination Gloves; Reclassification and Medical Glove Guidance Manual Availability; Proposed Rule and Notice

Dear Dr. Henney:

The American College of Surgeons is pleased to have the opportunity to comment on the proposed rule pertaining to surgeon's patient examination gloves. We realize this is a significant issue for patients who are concerned about the increased frequency of latex allergies. These concerns, of course, prompted the FDA to reclassify gloves as Class II medical devices and propose regulations for their manufacture. We believe the proposed rule succeeds in balancing the need to reduce the incidence of allergic reactions with the manufacturers' desire to avoid development of new and expensive production methods.

Because this proposal deals with many topics that are outside the realm of surgeons' experience and expertise, we have selected to keep our views very focused on how the use of latex gloves relates to patient care. In fact, we are centering our remarks only on Section VI of the proposed rule and responding to the specific concerns raised by the agency. The specific topics of interest and our responses follow.

Timeframes

The FDA prefers a one-year effective date, but is proposing a two-year effective date based on indications from the manufacturers that a shortage of medical gloves could result. The College, however, would note that production and use of powder-free and low-protein content gloves has increased dramatically in recent years. Further, these trends are likely to continue in

C4

response to concerns about lawsuits filed by patients with latex allergies. Hence, we would encourage the FDA to follow its preferences on this topic and implement a one-year effective date.

Powder Limit

The FDA is recommending a limit of 120 mg of powder per glove, regardless of size, in order to reduce exposure to particles and airborne allergens. Currently, the powder limit for surgeons' gloves in active use ranges from 70 mg to 375 mg. For examination gloves, the range is 50 mg to 428 mg. Thus, it is reasonable to say that no more than 100 mg of powder is necessary for donning. We suggest that the powder limit be set at 100 mg or less per glove.

Additional Labeling

The FDA requests comments on the feasibility and desirability of additional labeling requiring manufacturers to state the primary ingredients in glove powder. The College believes that manufacturers should be required to list on glove labels the primary ingredient in the powder to help protect our patients from possible allergens.

Powder Limit on "Powder-Free" Gloves

The FDA is recommending no more than 2 mg of powder per glove, regardless of size, as the powder limit for those gloves labeled "powder-free." The proposed limit of 2 mg per glove is reasonable. The amount of powder should not affect barrier properties, as they are primarily influenced by protein levels and the amount of chlorine used in production. Additionally, the quality control of chlorine processing has a significant effect on glove shelf-life. The requirements for labeling shelf-life should encourage the careful monitoring of chlorine use and, so, improve barrier protection and glove quality.

Requirement that Gloves be Powder-Free

The FDA is considering a future requirement that all surgeons' and patient gloves marketed in the U.S. be powder-free. The College agrees with the recommendation and believes there is no reason to continue the use of powdered gloves. Indeed, the elimination of powdered gloves will significantly lower the risk of allergic reactions. By making powder-free gloves the

standard, the FDA will reduce the incidence of allergic reactions from airborne protein particles carried to the medical staff using them and to the patient. Further, because the protein level in powder-free gloves is much lower, the gloves are less subject to hydration and, hence, retain their barrier qualities.

Limit on Protein Content

The FDA is recommending an upper limit of no more than 1,200μg of protein, regardless of size, as the maximum level for each natural latex gloves. The suggestion is sound. However, the agency should bear in mind that the necessary thickness of gloves varies depending upon the type of procedure for which they are being used, and thicker gloves generally have higher protein levels. This is especially true of the gloves used in orthopaedic procedures. Presently, the American Society of Testing and Manufacture (ASTM) is considering a new standard for glove protein levels based on the Enzyme Linked Immunesorbent Assay (ELISA). ELISA can detect protein levels considerable lower than the 50μg/g minimum under the existing standard ASTM D 5712 modified Lowry method. If this new measurement system is adopted, manufacturers should be allowed to claim less than 300μg per glove if the soluble protein level measured by ELISA is indeed less. Thus, if anything, a limit of 1,200 μg seems a bit generous given today's advanced manufacturing and testing capabilities.

Other Options for Protecting Public Health

In the notice of proposed rulemaking, the FDA seeks to reduce adverse health effects from allergic reactions and foreign body reactions by controlling the levels of water-extractable protein and glove powder on natural latex gloves. The FDA further seeks alternative approaches to achieving these objectives. Building on our previous response, we would suggest that the FDA start applying the ELISA test as the standard for detecting water soluble protein amounts. This step will help result in the production of gloves that have greater sensitivity and lower protein levels.

Recommended Versus Required Limits

The FDA is asking for advice on whether the limits on powder and protein proposed in the rule should serve as recommendations or requirements. To help promote patient care, the College advocates having the limits become requirements.

Air Handling Systems

The FDA considered requiring the use of a special air handling system at the point of use for those facilities using gloves with powder levels above 120mg, regardless of glove size. The College believes this requirement would place facilities in the position having to install costly, new ventilation systems. We believe it would be less burdensome to simply ban the use of powdered gloves, especially those with more than 120 mg of powder.

Exemption or Variance From Labeling Requirements

Finally, the College would like to comment on the FDA's question regarding whether to grant manufacturers permission to request exemptions or variances from the labeling requirements or if restrictions on distribution should be added to the proposed rule. The College opposes this concept because we believe that the labeling requirements and standards set in the proposed rule are feasible and necessary.

We hope our comments on various concerns raised in Section VI of the proposal on surgical and examination gloves are useful to the FDA. If you have any questions, or if the College may be of further assistance, please call the Washington office at (202) 337-2701.

Sincerely,

David L. Nahrwold

David Nahrwold, MD, FACS
Interim Director

HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

CROSS REFERENCE SHEET

Docket Number/Item Code:	99D-2335/C4
See Docket Number/Item Code:	98N-0313/C22

SPAT 1

FedEx USA Airbill

FedEx Tracking Number 810429849120

Form I.D. No. 0210

Recipient's Copy

1 From

Date 10/26/11

Sender's Name [redacted] Phone 202 337-2701

Company AMERICAN COLLEGE OF SURGEONS

Address 1640 WISCONSIN AVE NW Dept./Floor/Suite/Room

City WASHINGTON State DC ZIP 20007

2 Your Internal Billing Reference Information

3 To

Recipient's Name Jane Henney MD Phone ( )

Company Food and Drug Administration

Address 5630 Fishers Lane, Room 1061 Check here if residence (Extra charge applies for FedEx Express Saver)

To "HOLD" at FedEx location, print FedEx address here. Dept./Floor/Suite/Room

City Rockville State MD ZIP 20852

For HOLD at FedEx Location check here

- Hold Weekday (Not available with FedEx First Overnight)
- Hold Saturday (Not available at all locations) (Available for FedEx Priority Overnight and FedEx 2Day only)

For WEEKEND Delivery check here (Extra Charge, Not available at all locations)

- Saturday Delivery (Available for FedEx Priority Overnight and FedEx 2Day only)
- NEW Sunday Delivery (Available for FedEx Priority Overnight only)

8 1 0 4 2 9 8 4 9 1 2 0

4a Express Package Service *Packages under 150 lbs.* Delivery commitment may be later in some areas.

- [x] FedEx Priority Overnight (Next business morning)
- [ ] FedEx Standard Overnight (Next business afternoon)
- [ ] FedEx First Overnight (Earliest next business morning delivery to select locations) (Higher rates apply)
- [ ] FedEx 2Day (Second business day)
- [ ] FedEx Express Saver (Third business day)

FedEx Letter Rate not available. Minimum charge: One pound rate.

4b Express Freight Service *Packages over 150 lbs.* Delivery commitment may be later in some areas.

- [ ] FedEx Overnight Freight (Next business day)
- [ ] FedEx 2Day Freight (Second business day)
- [ ] FedEx Express Saver Freight (Up to 3 business days)

(Call for delivery schedule. See back for detailed descriptions of freight services.)

5 Packaging

- [x] FedEx Letter
- [ ] FedEx Pak
- [ ] FedEx Box
- [ ] FedEx Tube
- [ ] Other Pkg.

Declared value limit $500.

6 Special Handling (One box must be checked)

Does this shipment contain dangerous goods?*

- [ ] No
- [ ] Yes (As per attached Shipper's Declaration)
- [ ] Yes (Shipper's Declaration not required)

- [ ] Dry Ice — Dry Ice, 9, UN 1845 ____ x ____ kg
- [ ] Cargo Aircraft Only

*Dangerous Goods cannot be shipped in FedEx packaging.

7 Payment

Bill to:

- [x] Sender (Account No. in Section 1 will be billed)
- [ ] Recipient
- [ ] Third Party
- [ ] Credit Card
- [ ] Cash/Check

(Enter FedEx Account No. or Credit Card No. below)

- [ ] Obtain Recipient FedEx Account No.

Total Packages	Total Weight	Total Declared Value*	Total Charges
		$ .00	$

* When declaring a value higher than $100 per shipment, you pay an additional charge. See SERVICE CONDITIONS, DECLARED VALUE, AND LIMIT OF LIABILITY section for further information.

Credit Card Auth.

8 Release Signature

Your signature authorizes Federal Express to deliver this shipment without obtaining a signature and agrees to indemnify and hold harmless Federal Express from any resulting claims.

321

Questions?
Call 1·800·Go·FedEx® (800)463-3339

0086114808

WCSL 1298
Rev. Date 7/98
Part #153023ps
©1994-98 FedEx
PRINTED IN U.S.A.